

## REMARKS

### A. Amendments

Support for the amendment of Claim 44 may be found in cancelled Claim 49.

Support for the amendment of Claim 48 may be found in Example 3 and Figures 7 through 12. In Example 3, the fractionation is discussed ("a xanthine free alkaloid subfraction was submitted to further subfractionation to yield five subfractions designated MM2A to MM2E"). Figures 7A to 7H show the dose responses of fractions A+B, A+E, and A+D; Figures 8A to 8H show the dose responses of fractions A+B, B+E, and D+E; Figures 9A to 9H show the dose responses for fractions B+D, A+D, and D+E; Figures 10A to 10H show the dose responses for fractions B+D, C+D, and A+E; Figures 11A to 11H show the dose responses for fractions A+E and C+E; Figures 12A to 12H show the dose responses for fractions B+C, C+D, and D+E; Figures 13A to 13H show the dose responses for fractions B+C, C+E, and D+E.

The dependencies of Claims 46 and 50-59 have been corrected.

### B. Specification

The specification is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. Because of the differences between the instant specification and the parent applications, the Examiner has requested a substitute specification which reintroduces the missing text of original pages 47-52.

Applicants had intended to provide the substitute specification when the last Amendment was filed. It is filed herewith. It is a copy of the specification filed in grandparent application Ser. No. 08/317,266 filed October 3, 1994. No new matter is presented in the substitute specification.

C. Rejection of Claims 44, 46-55, and 59 Under §112, 2<sup>nd</sup> Paragraph

Claims 44, 46-55, and 59 are rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as indefinite.

Claim 44 is indefinite because it is unclear if the food or the food additive comprises the recited mixture of cocoa polyphenols. In view of the Amendment of the Claim 44, it should now be clear that it is the mixture of cocoa polyphenols that is the food additive.

Claim 46 is indefinite because it depends from canceled Claim 45. In view of the amendment of Claim 46 to change the dependency to Claim 44, the rejection is overcome.

Claim 48 is indefinite because the phrase "wherein certain cocoa procyanidin fractions are selected and pooled" does not indicate which fractions from Claim 47 are actually selected and pooled. In view of the amendment of the claim to indicate that "two or more fractions of the cocoa procyanidins are pooled", it is believed the rejection is overcome.

D. Obviousness-type Double Patenting Rejection Over Claims 1-3 and 13 of U.S. 5,554,645

Claims 44, 46-55, and 59 are rejected under the judicially created doctrine of obviousness-type double patenting over Claims 1-3 and 13 of U.S. Patent No. 5,554,645 for the reasons set forth in the previous Office action.

Applicants' arguments with respect to the obviousness-type double patenting rejection have been carefully considered but are not deemed persuasive. The Examiner believes it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the cocoa extract preservative of Claim 13 of '645 patent to a foodstuff to preserve the foodstuff, especially since the addition of preservatives to foodstuff is notoriously well known to prolong freshness and/or storage by inhibiting spoilage of the food. The Examiner also believes the phrase "consisting essentially of" reads upon "comprising" especially with respect to a food comprising the claimed cocoa extract.

E. Applicants' Response To Obviousness-Type Double Patenting Rejection Over  
U.S. 5,554,645

It is respectfully pointed out that only Claim 13 is directed to an antioxidant or preservative composition and that Claim 13 depends on Claim 1. The inclusion of Claims 1-3 in rejection appears to be an oversight.

Applicants do not agree that "consisting essentially" reads on "comprising". The claimed cocoa extract cannot be the same as the "substantially pure cocoa extract" of Claim 13 because that claim was narrowed during prosecution to exclude monomers and dimers. The present cocoa extract specifically recites the monomers catechin and epicatechin and Claim 46(44) specifically recites dimers.

As originally filed in Ser. No. 08/317,226, which matured into the '645 patent, Claim 1 (upon which original Claim 13 depended) read: "A substantially pure cocoa extract comprising cocoa polyphenol(s)." During prosecution the claim was amended to change "comprising" to "consisting essentially of" and to identify the polyphenols as "oligomers 3 through 12". At the same time original Claim 5(1) was amended to delete reference to the monomer (-)-epicatechin as well as dimers procyanidin B-2 and procyanidin A-2. In the same Amendment original Claim 22 (Claim 13 of the '645 patent) was amended to change the transitional language after "antioxidant or preservative composition" from "comprising" to "consisting essentially of". See pages 2 and 3 from the Amendment mailed October 20, 1995 attached as Exhibit 1.

It is respectfully submitted that the cocoa extract in Applicants' food claims is not an obvious variant of the cocoa extract of Claim 13 of the '645 patent because it includes the monomers which were excluded from the cocoa extract of Claim 13.

F. Obviousness-Type Double Patenting Rejection of Claims 44 and 46 Over U.S. 6,399,139

Claims 44 and 46 are rejected under the judicially created doctrine of obviousness-type double patenting over Claims 1-20 of U.S. Patent No. 6,399,139 for the reasons of record.

In view of the amendment of Claim 44 to include the limitations of Claim 49, it is believed the rejections are overcome.

G. Obviousness-Type Double Patenting Rejection of Claims 44, 46-55, and 59 Over Serial No. 09/768,473

Claims 44, 46-55, and 59 are rejected under the judicially created doctrine of obviousness-type double patenting over the claims of copending Application Ser. No. 09/768,473 for the reasons of record. The '473 application is allowed and the issue fee has been paid.

As was set forth in the previous Office Action, the Examiner believes the inventions are not patentably distinct because both are apparently directed to foods. Applicants argue that the claims of the '753 application contain no food claims. However, as is the case with the '645 claims, the Examiner believes that it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the claimed cocoa extract to a foodstuff so as to beneficially preserve the foodstuff, especially since the addition of preservatives to foodstuffs is notoriously well known and accepted in the art to advantageously prolong its freshness and/or storage by inhibiting spoilage thereof.

H. Applicants' Response To Obviousness-Type Double Patenting Rejection Over Ser. No. 09/768,473

It is again pointed out that the claims of the '473 application are directed to "a partially purified, solvent derived cocoa extract comprising epicatechin, catechin, and procyanidin

oligomers of epicatechin and/or catechin". It is respectfully submitted that foods containing a cocoa extract and the cocoa extract *per se* are patentably distinct products – they are not obvious variants of one another.

I. Rejections of Claims 44 and 46 under §102(b)

Claims 44 and 46 are rejected under §102(b) as being anticipated by Zieglader et al. (CCB Rev., 1983), Omori (JP 08205818 – JPAB Abstract), Maruyama et al. (JP 04077424), Kattenberg (US 4,704,292), Helmona AG (FR 2307779 – DWPI Abstract & French patent), Osakabe et al. (JP 7-274894 – English translation), or Osakabe et al. (JP 7-213251 – English translation), with evidence provided by Hammerstone et al. (J. Argicult. Food Chem., 1999). The Examiner notes that Hammerstone et al. is not being cited as prior art, but instead as evidence to show that various prior art cocoa extracts inherently contain polyphenols such as those claimed.

In view of the amendment of Claim 44 to include the limitations of Claim 49, it is believed the rejections are overcome.

J. Rejections of Claims 44 and 46 Under 35 U.S.C. § 103

Claims 44 and 46 are rejected under 35 U.S.C. 103(a) as being obvious over Zieglader et al. (CCB Rev., 1983), Omori (JP 08205818 – JPAB Abstract), Maruyama et al. (JP 04077424), Kattenberg (US 4,704,292), Helmona AG (FR 2307779 – DWPI Abstract & French patent), Osakabe et al. (JP 7-274894 – English translation), Osakabe et al. (JP 7-213251 – English translation), and Kashket (US 4,906,480), and (if necessary) in view of Clappertone et al. (XVI Intl. Conf. of Groupe Polyphenols, 1992), with evidence provided by Hammerstone et al. (J. Agricult. Food Chem., 1999). The Examiner notes that Hammerstone et al. is not being cited as

prior art, but instead as evidence to show that various prior art cocoa extracts inherently contain polyphenols such as those claimed.

In view of the amendment of Claim 44 to include the limitations of Claim 49, it is believed the rejections are overcome.

K. Closing

Withdrawal of the §102(b), §103(a), and §112 rejections is respectfully requested. Reconsideration and withdrawal of the obviousness-type double patenting rejections is also respectfully requested.

A marked-up version showing changes to the claims is attached.

Respectfully submitted,

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## MARKED-UP VERSION SHOWING CHANGES

44. (amended twice) A food comprising a mixture of cocoa polyphenols as a food additive, [isolated from cocoa beans as a cocoa extract, which comprises catechin, epicatechin, and procyanidin oligomers thereof.] the cocoa polyphenol mixture comprising catechin, epicatechin, and cocoa procyanidin oligomers thereof and being prepared by reducing cocoa beans to a cocoa powder, defatting the cocoa powder, and extracting the cocoa polyphenols from the cocoa powder.

46. (amended twice) The food of Claim [45] 44, wherein the procyanidin oligomers are selected from the group consisting of dimers through dodecamers.

48. (amended twice) The food of Claim 47, wherein [certain] two or more of the cocoa fractions are [selected and then] pooled.

50. (amended once) The food of Claim [49] 59, wherein the freeze dried cocoa beans are unfermented cocoa beans.

51. (amended once) The food of Claim [49] 59, wherein the freeze dried cocoa beans are partially fermented cocoa beans.

52. (amended once) The food of Claim [49] 59, wherein the freeze dried cocoa beans are fermented cocoa beans.

53. (amended once) The food of Claim [49] 44, wherein the extracting is carried out with acetone and water, methanol and water, or ethyl acetate.

54. (amended once) The food of Claim [49] 44, wherein the cocoa extract is partially purified by gel permeation chromatography and/or high pressure liquid chromatography.

59. (amended once) The food of Claim [49] 44, wherein [the process of] reducing the cocoa beans to [a] the cocoa powder comprises the steps of[:] freeze drying the cocoa beans and pulp[:], depulping the freeze dried cocoa mass[:], dehulling the freeze dried cocoa beans[:], and grinding the dehulled cocoa beans.



Exhibit 1

IN THE CLAIMS:

Please amend the claims as follows:

1. (Amended) A substantially pure cocoa extract or synthetic polyphenol(s) consisting essentially of [comprising cocoa] polyphenol(s) of oligomers 3 through 12.

5. (Amended) The extract or synthetic polyphenol(s) of claim [4] 1 [containing] consisting essentially of polyphenol(s) of [at least one cocoa procyanidin selected from the group consisting of: (-)-epicatechin, procyanidin B-2, procyanidin] oligomers [4] 5 through 12[, procyanidin B-5, procyanidin A-2 and procyanidin C-1].

6. (Amended) An antineoplastic composition consisting essentially of the [comprising a] substantially pure cocoa extract or synthetic cocoa polyphenol(s) as claimed in claim 5 and a suitable carrier.

8. (Amended) The antineoplastic composition of claim [7] 6 wherein the cocoa procyanidin(s) are prepared from a process comprising:

reducing cocoa beans to powder,  
defatting the powder, and,  
extracting the cocoa procyanidin(s) from the  
powder.

18. (Amended) A kit for treating a patient in need of treatment with an antineoplastic agent consisting essentially of

the [comprising a] substantially pure cocoa extract or synthetic [cocoa] polyphenol(s) as claimed in claim 5 and a suitable carrier.

19. (Amended) The kit of claim 18 wherein [the antineoplastic agent is comprised of a substantially pure cocoa extract containing procyanidin(s); and,] the kit includes instructions for admixture of ingredients [and/]or administration to the patient.

20. (Amended) A lyophilized antineoplastic composition consisting essentially of the [comprising a] substantially pure cocoa extract or synthetic [cocoa] polyphenol(s) as claimed in claim 5.

22. (Amended) An antioxidant or preservative composition consisting essentially of the [comprising a] substantially pure cocoa extract or snythetic polyphenol(s) as claimed in claim 1 [or synthetic cocoa polyphenol(s)].

Claim 23, line 2, please change "comprising a" to --consisting essentially of the--.

Please cancel claims 7, 11 to 17 and 21 without prejudice.

#### REMARKS

Reconsideration and withdrawal of the objections to and rejections of this application are respectfully requested in view of the amendments, remarks and enclosures herewith.